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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,182	12/21/2001	Karl Tryggvason	99,274-F	8557
20306	7590	09/21/2004	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			CARLSON, KAREN C	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/037,182	Applicant(s) TRYGGVASON ET AL.	
	Examiner Karen Cochran Carlson, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 13, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10, 17 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 5 is/are allowed.
- 6) ☐ Claim(s) 6-10, 17 and 23 is/are rejected.
- 7) ☐ Claim(s) 24 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1653

This Office Action is in response to the paper filed August 13, 2004. Claims 1-4, 11-16, and 18-22 have been cancelled. Claims 5-10 17, and 23-25 are currently pending and are under examination.

Priority for the $\alpha 5$ SEQ ID NO: 2 is to SN 60/257,449 filed December 21, 2000 for the alpha chain, and SN 60/279,282 filed March 28, 2001 for laminin 10

It is noted that high stringency conditions for hybridization are specifically defined at page 19 of the specification.

Withdrawal of Objections and Rejections

The rejection of Claim 17 under 35 U.S.C. 112, second paragraph, is withdrawn.

Maintenance of Objections and Rejections

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 20, line 6. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

It appears that Applicants intended to delete this hyperlink. However, the hyperlink was not deleted in the amendment to the specification. Therefore, this objection is maintained.

As noted in the previous Office Action:

The following Table shows the % identity between the sequences set forth in the claims and those found for Mouse and for Human sequences

<u>SEQ ID NO</u>	<u>% identity to Mouse</u>	<u>% identity to Human</u>
$\alpha 5$ 2	78.7	99.9
$\alpha 5$ 4	100	79.7
$\beta 1$ 6	100	93.7
$\beta 1$ 8	100	93.2
$\beta 1$ 10	100	93.7

Art Unit: 1653

β 1	12	100	94.1
γ 1	14	93.7	100
γ 1	16	94.3	100
γ 1	18	99.2	93.7
γ 1	20	99.2	94.2

A search of the sequences against the following references were used to provide the information in the Table above:

Miner et al. (1995. J. Biol. Chem. 270:28523-28526) for SEQ ID NOs: 2 & 4.

Durkin et al. (1997. FEBS Lett 411: 296-300) for SEQ ID NOs: 2 & 4.

Sasaki et al. (1987. P.N.A.S. 84: 935-939) for SEQ ID NOs: 6, 8, 10, & 12.

Pikkarainen et al. (1987.J. Biol. Chem 262:10454-10462) for SEQ ID NOs: 6, 8, 10, & 12.

Sasaki et al. (1987. J. Biol. Chem 262: 17111-17117) for SEQ ID NOs: 14, 16, 18, & 20.

Pikkarainen et al. (1988.J. Biol. Chem 263:6751-6758) for SEQ ID NOs: 14, 16, 18, & 20.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10, 17, and 24 are again rejected under 35 U.S.C. 102(b) as being anticipated by Miner et al. (1997; J. Cell Biol. 137(3): 685-701). Miner et al. teach isolated mouse laminin 10 hetero-trimers comprising α 5 chain, β 1 chain, and γ 1 chain (see Fig. 10B and page 700, left col. para. 1; Claim 6). Because laminin 10 isolated from natural sources does not differ from recombinantly produced laminin 10, Claim 7 is included in this rejection. Claim 10 is anticipated because the limitation "R3" is met, as is "R3e" because the laminin 10 was isolated via antibody. Given the high identity across species of laminin chains (as evidenced in Miner et al. by rat antibody recognizing mouse laminin 10 and by the Table set forth above), one skilled in the art

Art Unit: 1653

would surmise that the chains found in the mouse laminin 10 of Miner et al. would have at least 70% identity to the sequences set forth in Claim 9 and 17, and/or be encoded by polynucleotides that would hybridize to the sequences of Claim 8. Indeed, at page 30, line 16 of the specification, SEQ ID NO: 3 depicts cDNA encoding mouse $\alpha 5$. Pharmaceutical compositions of laminin 10 is found at page 687, col. 1, para. 4 (Claim 23).

Applicants urge that the laminin 10 of Miner et al. is not substantially free of other proteins because it is present with laminin 11. It is not clear to the Examiner what Applicants consider to be "substantially free of other proteins", that is, this phrase does not mean that laminin 10 is isolated from all other proteins. Also, the term "isolated" is a patent term meaning "taken from its natural source" or acted on "by the hand of man". Therefore, this rejection is maintained.

New Objections

Claims 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

Art Unit: 1653

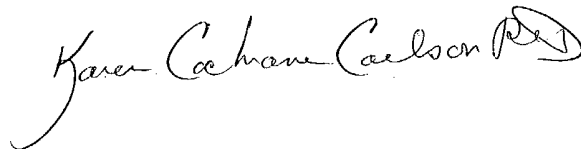
calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim 5 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER